K062785

510(k) Summary

DEC 26 2006

Manufacturer:
US Spine
3600 FAU Blvd., Suite 101
Boca Raton, FL 33431

Submitted By:
Richard Jansen, Pharm. D.
Silver Pine Consulting
13540 Guild Ave.
Apple Valley, MN 55124
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Proprietary Name:
LTD Polyaxial Fixation System

Classification Name:
Appliance, Fixation, Spinal

Common/Usual Name:
Pedicle Screw Spinal System

Classification:
Class II (888.3050, 888.3060, 888.3070)

Product Codes:
MNH, MNI, KWP, KWQ

Predicate Devices:
K980447 – Moss Miami Pedicle Fixation System
K984251 – Stryker Spine Xia Spine System
K031585 – Optima Spine System

Device Description:
The LTD Polyaxial Fixation System consists of a variety of shapes and sizes of rods, screws and connecting components, sold with or without the surgical instrument tray. These components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. The LTD Polyaxial Fixation System implant components are fabricated from medical grade titanium or titanium allow described by such standards at ASTM F67 or ASTM F136 for ISO 5832-2/3.

This Pre-market Notification adds 5.5mm rods and associated polyaxial screws to the LTD Polyaxial System.

Indications for Use:
The LTD Polyaxial Fixation System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the lumbar and/or sacral spine, specifically as follows:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the LTD Polyaxial Fixation system is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) spinal tumor, and/or (5) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the LTD Polyaxial Fixation System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the LTD Polyaxial Fixation System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) fracture, (5) pseudarthrosis, (6) tumor resection and/or (7) failed previous fusion.

Performance Data:

Biomechanical testing included a static axial compression bending test, static torsion test and dynamic axial compressing bending test. All tests met the acceptance criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

US Spine
% Richard Jansen, Pharm. D
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13540 Guild Ave
Apple Valley, Minnesota 55124

DEC 26 2006

Re: K062785
Trade/Device Name: LTD 5.5 Polyaxial Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP, KWQ, MNI, MNH
Dated: November 22, 2006
Received: November 27, 2006

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Barbara Buchmo

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K062785

Device Name: LTD Polyaxial Pedicle Fixation System

Indications for Use:

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Prescription Use √	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buch MD

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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